DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 8, 2015

Xeridiem (formerly Mri)
Jesus Valencia
RA Specialist
4700 S. Overland Dr.
Tucson, AZ 85714

Re: K142297
Trade/Device Name: EndoVive™ 3s Low Profile Balloon Kit
EndoVive™ 3s Bolus Extension Sets
EndoVive™ 3s Continuous Extension Sets
EndoVive™ 3s Medication Extension Set
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PIF, PIO
Dated: December 4, 2014
Received: December 5, 2014

Dear Jesus Valencia,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142297

Device Name
EndoVive 3S Low Profile Balloon Kit and Extension Sets

Indications for Use *(Describe)*

The EndoVive 3S Low Profile Balloon is indicated for use in adult and pediatric patients who require long term feeding, are unable to tolerate oral feeding, are at low risk for aspiration or require gastric decompression and/or medication delivery directly into the stomach.

The EndoVive 3S Extension Set is indicated for the delivery of nutrition, hydration and/or medication into the stomach through a low profile balloon and also provides a mechanism for gastric decompression.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

(End of Section)

510(k) Summary

As required by 21 CFR 807.92, this "510(k) Summary" provides a basis for the substantial equivalence determination of the subject device listed below. This "510(k) Summary" was prepared in adherence to the guidelines provided in *FDA Guidance - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].*

Submitter Information

Date Prepared: January 6th, 2015

510(k) Submitter:
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510(k) Correspondent: Same as above

Subject (Proposed) Device Information

Trade Name: EndoVive™ 3S Low Profile Balloon Kit and EndoVive™ 3S Extension Sets

Common Name: Low Profile Balloon Gastrostomy Tube and Feeding/Medication Extension Sets

Classification Name: Gastrointestinal Tubes with Enteral Specific Connectors and Enteral Specific Transition Connectors
[21 CFR 876.5980, Product Code PIF and PIO]

Classification Panel: Gastroenterology/Urology

Class: Class II

Primary Predicate Device Information

Trade Name: MIC-KEY® Low Profile Gastrostomy Tube

Common Name: Low Profile Balloon Gastrostomy Tube

Classification Name: Tubes, gastrointestinal (and accessories)
[21 CFR 876.5980, Product Code KNT]

Classification Panel: Gastroenterology/Urology

Class: Class II

510(k) Number: K043114

Secondary Predicate Device Information

Trade Name: AMT Mini ONE® Balloon Button Low Profile Gastrostomy Device

Common Name: Low Profile Balloon Gastrostomy Tube

Classification Name: Tubes, gastrointestinal (and accessories)
[21 CFR 876.5980, Product Code KNT]

Classification Panel: Gastroenterology/Urology

Class: Class II

510(k) Number: K971434

Device Description

Device Identification:

The following is a list and brief description of the components and model variations of the proposed devices.

- **EndoVive™ 3S Low Profile Balloon Kit:**

  The EndoVive™ 3S Low Profile Balloon Kit contains an EndoVive™ 3S Low Profile Balloon which is a sterile, low profile balloon gastrostomy tube. Table 5.1 lists the varying size offerings for the EndoVive™ 3S Low Profile Balloon. The kit also contains the following accessories which are intended to facilitate placement and use of the EndoVive™ 3S Low Profile Balloon: Continuous and Bolus feeding extension sets, a stiffener, transition adapters, syringes, lubricating jelly, gauze pads and a patient care bag.

Table 5.1 – EndoVive™ 3S Low Profile Balloon Device Offerings

Description	EndoVive™ 3S Low Profile Balloon Configurations						
	12 Fr	14 Fr	16 Fr	18 Fr	20 Fr	22 Fr	24 Fr
Stoma Lengths (cm)	0.8	0.8					
	1.0	1.0	1.0	1.0	1.0	1.0	
	1.2	1.2	1.2	1.2	1.2	1.2	
	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	1.7	1.7	1.7	1.7	1.7	1.7	1.7
	2.0	2.0	2.0	2.0	2.0	2.0	2.0
	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	2.5	2.5	2.5	2.5	2.5	2.5	2.5
	2.7	2.7	2.7	2.7	2.7	2.7	2.7
	3.0	3.0	3.0	3.0	3.0	3.0	3.0
	3.5	3.5	3.5	3.5	3.5	3.5	3.5
	4.0	4.0	4.0	4.0	4.0	4.0	4.0
		4.5	4.5	4.5	4.5	4.5	4.5
		5.0	5.0	5.0	5.0	5.0	5.0
		5.5	5.5	5.5	5.5	5.5	5.5
		6.0	6.0	6.0	6.0	6.0	6.0
		6.5	6.5	6.5	6.5	6.5	6.5
Recommended Balloon Fill Volume (mL)	4	4.5	5	6	7	8	10

- **EndoVive™ 3S Extension Sets:**

  The following extension sets will be sold separately in a non-sterile 5-pack configuration.

Table 5.2 – EndoVive™ 3S Extension Set Offerings

Extension Set (ES) Type	Tubing Diameter (French)	Tubing Length (in)	Connector Profile (ES-to-feeding port of low profile g-tube)	Port Profile (Enteral access devices-to-ES)	Adapters included in packaging	
					Feeding Port Transition Adapter	Medication Port Transition Adapter
EndoVive™ 3S Continuous Feeding Extension Set	12	12	Right-angle	Y-port	X	X
	12	24	Right-angle	Y-port	X	X
EndoVive™ 3S Bolus Feeding Extension Set	20	12	Straight	Single Port		X
	20	24	Straight	Single Port		X
	20	12	Right-angle	Single Port		X
	20	24	Right-angle	Single Port		X
EndoVive™ 3S Medication Extension Set	12	2	Right-angle	Y-port	X	

Device Characteristics:

The following is a brief description of the proposed device characteristics.

- **EndoVive™ 3S Low Profile Balloon Kit:**
  - Contains no software, biologics, drugs, coatings or additives
  - Contains patient contacting materials as described in Section 11 of this 510(k)
  - Is provided sterile for single patient use
  - Is sterilized using a 100% Ethylene Oxide (EO) sterilization process
- **EndoVive™ 3S Extension Sets:**
  - Contains no software, biologics, drugs, coatings or additives
  - Contains patient contacting materials as described in Section 11 of this 510(k)
  - Are provided non-sterile for single patient use

Environment of Use:

As listed in Table 5.3, the proposed devices will be used in healthcare facilities, hospitals and in the home.

Brief Description of the Device:

The following is a description of the proposed devices' principle of operation and mechanism of action for achieving their intended affect. The following also describes the proposed conditions of use, anatomical location of use and user interface.

The low profile gastrostomy tube is normally placed in a clinical setting and can be replaced and used in both a clinical and home care setting. The extension sets and syringes included with the kit may also be used in both a clinical and home care setting.

Before using the EndoVive™ 3S Low Profile Balloon, the stoma tract must be measured and the tube size appropriate for the patient must be identified by the healthcare provider. The distal end of the tube is inserted through a gastrointestinal stoma tract and into the stomach. Then the balloon is inflated with sterile or distilled water. The fitment of the tube is verified by ensuring that the external bolster is flush against the abdomen.

Extension sets are connected to the feeding port of the low profile gastrostomy tube to begin enteral administration and gastric decompression. The male ENFit connectors attached to the proposed devices are then connected to enteral sets and syringes incorporating female ENFit connectors. If enteral accessories incorporating female ENFit connectors are not available, the feeding port and medication port transition adapters may be connected to the male ENFit connectors to allow access to commonly available enteral administration sets and syringes. The male ENFit connectors attached to the EndoVive™ 3S Extension Sets were designed to reduce the likelihood of unwanted connections between enteral and non-enteral connectors. Until the ENFit connectors become widely available, the ENFit transition adapters will be provided with the EndoVive™ 3S Low Profile Balloon Kit to mitigate the risk of inaccessibility to care within the use environment.

Materials of Use:

The general types of materials used for the proposed devices consist of silicones, thermoplastics and non-DEHP PVC materials. The device materials conform to *AAMI/ANSI/ISO 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.* A more detailed, itemized table of the proposed device materials and associated types of contact and duration is included in Section 11 of this 510(k).

Key Performance Specifications/Characteristics of the Device:

Key performance specifications and device characteristics were derived from device-specific functionality and performance standards such as *ASTM F2528-06 - Standard Test Methods for Enteral Feeding Devices with a Retention Balloon*, *AAMI/ANSI/ISO 80369-1* and *EN 1615 - Enteral feeding catheters and enteral giving sets for single use and their connectors: Design and testing*. These standards are applicable for gastrostomy tubes and accessories such as those encompassed in the proposed and predicate devices. A more detailed description of device performance testing is included in Section 18 of this 510(k).

Intended Use

The EndoVive™ 3S Low Profile Balloon is intended to provide gastric access through a gastrointestinal stoma tract for enteral feeding, medication administration and gastric decompression.

The EndoVive™ 3S Extension Set is intended to connect to a low profile balloon for enteral feeding, medication administration and gastric decompression.

Indications for Use

The EndoVive™ 3S Low Profile Balloon is indicated for use in adult and pediatric patients who require long term feeding, are unable to tolerate oral feeding, are at low risk for aspiration or require gastric decompression and/or medication delivery directly into the stomach.

The EndoVive™ 3S Extension Set is indicated for the delivery of nutrition, hydration and/or medication into the stomach through a low profile balloon and also provides a mechanism for gastric decompression.

Comparison of Technological Characteristics with the Predicate Device

The device comparison table below provides a general summary of the technological characteristics of the proposed device compared to the predicate device. The proposed device is most similar to the device identified as the primary predicate. The secondary predicate device was chosen to demonstrate substantial equivalence for a few select features. These features are identified with the subscript *"(1)"* in Table 5.3.

Table 5.3 – Device Comparison Table

	Proposed Device **EndoVive™ 3S Low Profile Balloon Kit and Extension Sets**	**Primary Predicate Device** **MIC-KEY Low Profile Gastrostomy Tube** K043114	**Secondary Predicate Device** **AMT Mini One Balloon Button Low Profile Gastrostomy Tube** K971434
Class (FDA)	II	II	II
FDA Product Code	PIF / PIO	KNT	KNT
FDA Regulation	876.5980	876.5980	876.5980
Indications for Use	The EndoVive™ 3S Low Profile Balloon is indicated for use in adult and pediatric patients who require long term feeding, are unable to tolerate oral feeding, are at low risk for aspiration or require gastric decompression and/or medication delivery directly into the stomach. The EndoVive™ 3S Extension Set is indicated for the delivery of nutrition, hydration and/or medication into the stomach through a low profile balloon and also provides a mechanism for gastric decompression.	The MIC-KEY® Low Profile Gastrostomy Tube is designed as a replacement gastrostomy tube for use in a mature gastric stoma when a low profile device would benefit the patient. Gastrostomy tubes are indicated for patients with inability to swallow, other neurological disorders, and other conditions for which tube feeding would benefit the patient in the judgment of the physician.	The AMT Mini ONE® Balloon Button Low Profile Gastrostomy Device is indicated for providing nutrition directly into the stomach through an established stoma in a patient who is unable to consume nutrition by conventional means.
Operating Principle	Low profile gastrostomy tube tip enters though the stoma tract and into the stomach, then the device is secured in place by inflating the balloon. Extension sets are connected to the low profile gastrostomy tube and then enteral accessories connected to the extension sets to allow for administration of nutrients and medication into the stomach and for gastric decompression.	Low profile gastrostomy tube tip enters though the stoma tract and into the stomach, then the device is secured in place by inflating the balloon. Extension sets are connected to the low profile gastrostomy tube and then enteral accessories connected to the extension sets to allow for administration of nutrients and medication into the stomach and for gastric decompression.	Low profile gastrostomy tube tip enters though the stoma tract and into the stomach, then the device is secured in place by inflating the balloon. Extension sets are connected to the low profile gastrostomy tube and then enteral accessories connected to the extension sets to allow for administration of nutrients and medication into the stomach and for gastric decompression.
Clinical Conditions of Use			
For Use in Adult Patients	Yes	Yes	Yes
For Use in Pediatric Patients	Yes	Yes	Yes
For Use During Initial Placement Procedures	Yes	Yes(2)	No
For Use During Replacement Procedures	Yes	Yes	Yes
Environment of Use	Healthcare Facility Hospital Home	Healthcare Facility Hospital Home	Healthcare Facility Hospital Home

Single Patient Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Sterilization Method	ETO	ETO	ETO
Low Profile Gastrostomy Tube			
Balloon Material	Silicone	Silicone	Silicone
Shaft Material	Silicone	Silicone	Silicone
Balloon-to-Shaft Adhesive	Silicone Adhesive	Silicone Adhesive	Silicone Adhesive
Radiopaque Marker Materials	Barium/Silicone	Barium/Silicone	Barium/Silicone
External Bolster Material	Silicone	Silicone	Silicone
Feeding Valve Material	Thermoplastics/Silicone	Thermoplastics/Silicone	Thermoplastics/Silicone
Balloon Inflation Valve Material	Thermoplastics/Silicone/Metal Spring	Thermoplastics/Silicone/Metal Spring	Thermoplastics/Silicone/Metal Spring
Active (Functional) Tube Length Offerings	0.8-6.5 cm(1)	0.8-5.0 cm	0.8-6.5 cm(1)
French Size Offerings	12-24 FR	12-24 FR	12-24 FR
Packaging Configuration	PETG Tray w/ Tyvek lid	PETG Tray w/ Tyvek lid	PETG Tray w/ Tyvek lid
Kit Components			
Low Profile Gastrostomy Tube	Yes	Yes	Yes
Gauze Pads	Yes	Yes	Yes
Lubricating Jelly	Yes	No	No
Extension Sets	Yes	Yes	Yes
Inflation Syringe	Yes	Yes	Yes
Bolus Feeding Syringe	Yes	Yes	Yes
Stiffener (for shaft of low profile G-tube)	Yes(1)	No	Yes(1)
Feeding Port Transition Adapter (Female ENFit-to-Christmas tree-type connector)	Yes	No	No
Medication Port Transition Adapter (Female ENFit-to-luer connector)	Yes	No	No
Extension Sets			
Tubing Materials	Non-DEHP PVC	Non-DEHP PVC	Non-DEHP PVC

Connector Materials	Thermoplastic	Thermoplastic	Thermoplastic
Pinch Clamp Materials	Thermoplastic	Thermoplastic	Thermoplastic
Feeding Port Materials	Thermoplastic	Non-DEHP PVC	Non-DEHP PVC & Silicone
Medication Port Materials	Thermoplastic	Non-DEHP PVC	Non-DEHP PVC & Silicone
Feeding/Medication Port Tether	Pebax	Non-DEHP PVC	Non-DEHP PVC
Feeding/Medication Port Cap	Thermoplastic	Non-DEHP PVC	Non-DEHP PVC
Feeding Port Compatibility	ENFit Connectors Christmas Tree Connectors Catheter Tip Connectors	Christmas Tree Connectors Catheter Tip Connectors	Christmas Tree Connectors Catheter Tip Connectors
Medication Port Compatibility	ENFit Connectors Luer Slip/Lock Connectors	Luer Slip/Lock Connectors	Luer Slip/Lock Connectors
Offered in Separately Packaged Configurations	Yes	Yes	Yes

(1) **Note:** *Indicates proposed device features relying on substantial equivalence to the secondary predicate device.*
(2) **Note:** *The Indications for Use listed in the Directions for Use booklet for the legally marketed predicate states that the low profile gastrostomy tube may also be used during initial placement procedures and the indications listed in K043114 state that the device is used during replacement procedures.*

Discussion of Similarities and Differences

As outlined in Table 5.3, the proposed device and primary predicate device are similar in the following:

- Same intended use, in as far as that both are used for administration of enteral nutrition and gastric decompression, anatomical locations of use,
- Same environment and conditions of use,
- Similar indications for use, technological characteristics, general material types, principles of operation and mechanism of action,
- Both are provided in sterile, single patient use kits for facilitating placement and use of the low profile gastrostomy tube, and
- Both offer non-sterile, single patient use and separately packaged extension sets for user convenience.

As outlined in Table 5.3, the following are the differences between the proposed and primary predicate devices.

- The proposed device has a more comprehensive range of active length offerings for the low profile gastrostomy tube to better accommodate differing stoma tract lengths across the entire user profile of the device. The range of length offerings for the proposed device are identical to those of the secondary predicate device
- The proposed device kit includes a stiffener for select French size kits to facilitate insertion of the low profile gastrostomy tube through the stoma tract as does the secondary predicate device
- The proposed device kit includes water-soluble lubricating jelly for tube lubrication and to facilitate insertion of the low profile gastrostomy tube through the stoma tract
- The proposed device has male ENFit connectors attached to the extension set ports to reduce the likelihood of enteral misconnections and to fulfill the requirements of *FDA Draft Guidance: Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications* and *AAMI/ANSI/ISO 80369-1.* The male ENFit connectors were designed in accordance to the enteral connector specifications included in *FDA Device Master File (MAF # F2258) Related to Small Bore Connectors Intended for Enteral Applications*.
- The proposed device kit includes two additional transition adapters incorporating female ENFit connectors to ensure the proposed devices can be connected with enteral accessories commonly used across the spectrum of care as the market transitions to the new ENFit connector system for addressing enteral misconnections.

The differences identified in the technological characteristics of the proposed devices do not raise new questions of safety or efficacy. Performance (bench) testing as well as usability evaluations demonstrate that the proposed device is as safe and effective as its primary predicate device.

Performance Data

Nonclinical device performance testing was conducted for supporting substantial equivalence between the proposed and predicate devices. The bench tests addressed device performance characteristics such as:

- lumen/connector flow rate,
- balloon performance,
- internal leakage,
- tensile properties,
- connector performance which included the following tests,
    - fluid leakage,
    - stress cracking,
    - resistance to separation from axial load,

  - resistance to separation from unscrewing,
  - resistance to overriding, and
  - disconnection from unscrewing
- biocompatibility,
- sterilization,
- packaging,
- shelf life,
- dimensional analysis,
- enteral connector misconnection assessment,
- enteral connector risk management report,
- human factors/usability testing,
- failure modes and effects analysis (FMEA), and
- risk analysis

A more detailed description of the device performance testing is included in Section 18 of this 510(k). In conclusion, the proposed device performed equivalent to or better than the primary predicate device.

Conclusions Regarding Substantial Equivalence

In order to support substantial equivalence of the proposed device to its predicate, the following are provided among the information and summary tables included throughout this 510(k) submission: 1.) device description, 2.) indications for use, 3.) device comparison tables, 4.) material information, 5.) nonclinical (bench) test results, and 6.) product labeling. In particular, device performance test results demonstrate that there were no differences that are critical to the intended use of the proposed device or that affect the safety and effectiveness of the proposed device when used as labeled.

The proposed and predicate devices have the same intended use, in as far as that both are used for administration of enteral nutrition and gastric decompression, the same anatomical locations of use and the same environment and conditions of use. Further, the proposed and predicate devices have similar indications for use, technological characteristics, general material types, principles of operation and mechanism of action. The differences in technological characteristics of the proposed device have been identified and do not present any new issues of safety or effectiveness. Thus, the EndoVive™ 3S Low Profile Balloon and Extension Sets are substantially equivalent to the MIC-KEY® Low Profile Gastrostomy Tubes (K043114).

(End of Section)